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K030718

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CONFIDENTIAL

SCB Computer Motion Interface Controller
510(k) Summary

In accordance with 21 CFR section 807.92 Computer Motion, Inc. (CMI) is submitting the following 510(k) Summary:

1) Submitter Information

Computer Motion. Inc.
130-B Cremona Drive
Goleta, CA 93117

Contact: Cathy Stupak, Ph.D.

2) Name of Device:

Proprietary Name: SCB Computer Motion Interface Controller
Common Name: n/a
Classification Name: Laparoscope, General & Plastic Surgery
Regulation Number: 876.1500
Product Code: GCJ
Class: Class II.

3) Substantial Equivalence:
This submission establishes the substantial equivalence of the SCB Computer Motion Interface Controller to Computer Motion's HERMES® Port Expander

4) Description of the Device:
The SCB Computer Motion Interface Controller (SCIC) connects devices that are controlled by Computer Motion's voice-control system to the Storz Communication Bus (SCB) manufactured by Karl Storz.

The SCIC is tested to the following standards:

Test	Title
IEC 601-1	International Standard for Medical Electrical Equipment
IEC 601-1-1	International Standard for Medical Electrical Equipment
IEC 601-2-18	International Standard for Medical Electrical Equipment
UL 2601-1	Underwriters Laboratory

continued

Test	Title
EN55011/A1 CISPR 11	Conducted Emission
EN55011/A1 CISPR11	Radiated Emission
EN61000-4-2	Electrostatic Discharge
EN61000-4-3 and EN50140	RF Immunity
EN61000-4-4	EFT/Bursts Immunity
EN61000-4-5	Surge Immunity
EN61000-4-6	Conducted Immunity
EN60601-1	International Standard for Medical Electrical Equipment
EN60601-1-1	General Requirements for Safety – Collateral Standard
EN 60601-1-2	Emissions and Immunity Test Measurements
CAN/CSA-C22.2 No. 601.1	Medical Electrical Equipment Part 1, General Requirements for Safety, General Instructions Part 1
VA-19795	CMI Environmental Testing

5) Intended Use

The SCB Computer Motion Interface Controller is indicated for use with the Storz Communication Bus (SCB) manufactured by Karl Storz to connect HERMES-Ready™ devices to the SCB.

6) Technological Characteristics in Comparison to the Predicate

The predicate, the HERMES Port Expander, is an extension of the HERMES O.R. Control Center, providing 8 additional device connection ports for devices, whereas the SCIC is an extension of the Storz SCB, providing 8 additional device connection ports for devices.

8) Device Testing

Hazard analyses and hardware/software validations procedures were provided in this submission.

9) Conclusion drawn from the Device Testing

Data included in this submission demonstrate the safety and effectiveness of the SCB Computer Motion Interface Controller.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2003

Mr. Keith Lowrey
Regulatory Affairs Manager
Computer Motion, Inc.
130-B Cremona Drive
GOLETA CA 93117

Re: K030718
Trade/Device Name: SCB Computer Motion Interface Controller
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 GCJ
Dated: March 6, 2003
Received: March 7, 2003

Dear Mr. Lowrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K030718

Device Name: SCB Computer Motion Interface Controller

The SCB Computer Motion Interface Controller is indicated for use with the Storz Communication Bus (SCB) manufactured by Karl Storz to connect HERMES-Ready™ devices to the SCB.

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CRDH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)

David A Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030718